

Practitioner's Docket No. MPI97-035CP1M

REMARKS

Applicants herein cancel claims 2-4, 15, 16, 46, 47, 50, 58, and 59; and amend claim 6, claim 7, claim 10, claim 45, claim 49, claim 53, claim 55, and claim 57. No new matter has been added. Claims 6-7, 10-14 and 45, 49-50, and 53-57 remain pending and under consideration.

The Examiner has maintained claims 2-16 and 45-59 were rejected under 35 USC 112, first paragraph as failing to comply with the written description requirement. Applicants reiterate traversal of the rejection.

The Examiner objects to what structural features have been provided. As discussed in prior responses, Applicants submit the description of a polypeptide having at least 90% homology to either the entire sequence of SEQ ID NO:2 or at least 50 consecutive amino acids of SEQ ID NO:2 is clear to those of skill in the art. While more than one polypeptide falls within this range of structural homology, the determination to those of skill in the art of structural features which would fall within the scope is certainly clear and readily discernable and would be recognized to those of skill in the art as within the scope of applicants' disclosure at the time of filing of the application. Still further, Applicants have included limitations with a requirement of bioactivity of each of the claimed polypeptides.

Applicants further submit this reasoning is in accordance with guidance of the Office with regard to satisfaction of the Written Description Guidelines. For instance, applicants direct the Examiner's attention to Example 14 of the guidelines of the written description requirement, which acknowledges that a disclosure meets the requirements of written description where support for enzyme activity assays and percent homology are provided in the specification, along with support for one variant sequence.

However, in an effort to advance prosecution, Applicants have amended the claims. It is believed the present amendments render the rejection moot. Reconsideration and withdrawal of the rejection is requested.

Claims 2-16 and 45-59 were rejected under 35 USC 112, first paragraph as failing to comply with the enablement requirement. The rejection is traversed.

The Examiner has maintained the rejection for failure to meet the requirements of the enablement standard, asserting that one would not know which residues to add/subtract/change to maintain the desired activity, and that testing all the peptides is undue. Applicants respectfully traverse the rejection and maintain, as outlined in Applicants' prior response, while there may be numerous possibilities of peptides which fall within the structural parameters set forth in the claimed subject matter, the generation of all possibilities as well as assessment of bioactivities of the peptides would be no more than routine in view of the knowledge in the art in combination with Applicants' teaching. Applicants have provided guidance regarding generation of each of the possible derivatives of SEQ ID NO:2 which are at least 90% identical

(Page 5 of 6)

Practitioner's Docket No. MPI97-035CP1M

to SEQ ID NO:2, and/or would be well understood to one of skill in the art in view of the provided description in combination with the knowledge and skill in the art. As discussed, the number alone does not determine excessive, rather whether the experimentation is excessive or undue. The extent of undue experimentation is determined in view of the state of the art. Applicants submit, the number of possibilities of testing alone is not sufficient to maintain the present enablement rejection, as the tools to carry out such generation and/or identification of peptides, testing of bioactivities and identification of polypeptides having at least 90% identity to amino acid sequence of SEQ ID NO:2 and having an ACE2 bioactivity are in fact readily available to those of skill in the art in view of Applicants' disclosure and are no more than routine.

However, in an effort to advance prosecution, Applicants have amended the claims. It is believed the present amendments render the rejection moot. Reconsideration and withdrawal of the rejection is thus respectfully requested.

This paper is being filed timely as a petition for a one month extension is filed herewith. It is believed no additional fees or extensions of time are required. In the event any additional fees or extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

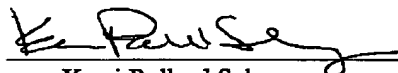
Entry of the remarks made herein is respectfully requested.

February 7, 2005

Respectfully submitted,

MILLENNIUM PHARMACEUTICALS, INC.

By



Kerri Pollard Schray
Registration No. 47,066
40 Landsdowne Street
Cambridge, MA 02139
Telephone - 617-551-3676
Facsimile - 617-551-8820